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8.0 510(k) Summary

510(k) Summary
(As Required by 21 C.F.R. §807.92)

Submitted by:

James Delaney
EXPERTech Associates, Inc.
100 Main Street, Suite 120
Concord, MA 01742
Tel: 978.371.0066 Fax: 978.371.1676

Date of summary: This summary was prepared on April 27, 2001.

Device name: The device names are the Nien Made HP-BPM0001, HP-BPM0002, HP-BPM0003, and HP-BPM0003-1 Non Invasive Blood Pressure (NIBP) Monitors.

Common name: Non Invasive Blood Pressure (NIBP) Monitors

Classification names:

Regulation Number & ProCode	Classification Name
21 CFR § 870.1130, ProCode 74 DXN	Non-Invasive Blood Pressure (NIBP) Monitor

Predicate Devices: Health & Life Ltd. HL-168B&C, HL-168, HL-168V, and HL-168T Non Invasive Blood Pressure (NIBP) Monitors.

Modifications: No modifications have been made.

Intended Use: For the measurement of systolic and diastolic blood pressure and heart rate using the oscillometric method as an over-the-counter device for persons age 16 and over.

Technological Characteristics: The Nien Made models operate using the oscillometric method. The system is microprocessor controlled and includes an air pump for automatic inflation, a deflation rate control valve, circuitry to detect and process minute pressure oscillations, and an LCD display. Two of the Nien Made models (HP-BPM0001 and HP-BPM0002) are based on push button operation and the other two models (HP-BPM0003 and HP-BPM0003-1) are based on touch screen operation.

For all models, the device is applied to the wrist and the user presses the start button or the center of the LCD touch screen to initiate the device. The pump then inflates the cuff to 180 mm Hg and will go higher if readings indicate the necessity. The cuff then slowly deflates and determinations of blood pressure, systolic and diastolic, and the pulse rate

are made. The exhaust valve is activated and the measurements are depicted on the LCD screen. The three models that have memory capabilities will automatically save the reading and the user is able to recall the last 14 readings. Additionally, the touch screen models offer date and time capabilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Nien Made Electronics Corporation
c/o Mr. James M. Delaney
EXPERTech Associates, Inc.
100 Main Street, Suite 120
Concord, MA 01742

Re: K011310
Trade Name: Nien Made Non-Invasive Blood Pressure Monitor, Models HP-BPM0001, HP-BPM0002, HP-BPM0003, HP-BPM0003-1
Regulation Number: 21 CFR 870.1130
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: April 27, 2001
Received: June 30, 2001

Dear Mr. Delaney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the

Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

JUL 2 0 2001

510(k) Number (if known) K011310

Device Name Nien Made HP-BPM0001, HP-BPM0002, HP-BPM0003, HP-BPM0003-1 Non-Invasive Blood Pressure (NIBP) Monitors.

Indications for Use For the measurement of systolic and diastolic blood pressure and heart rate using the oscillometric method as an over-the-counter device for persons age 16 and over.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011310

Prescription Use _____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)